AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Maryland on the following ☒ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT FOR THE DISTRICT OF MARYLAND
JFM-09-3062	11/17/09	101 W. Lombard Street, Baltimore, MD 21201

PLAINTIFF	DEFENDANT
Medicis Pharmaceutical Corporation	Lupin Ltd., et al

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	5,908,838		
2			
3			
4			
5			

In the above-entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading		
	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1			
2			
3			
4			
5			

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT

CLERK	(BY) DEPUTY CLERK	DATE
Felicia C. Cannon		11/18/09

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon) py to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director C

United States District Court For The District Of Maryland

V. COUNT FOR RELIEF
(INFRINGEMENT OF THE '838 PATENT BY DEFENDANTS)

35. The allegations of ¶¶ 1-34 are incorporated herein by reference.

36. On information and belief, Lupin Limited filed the Lupin ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent.

37. On or about October 8, 2009, Medicis received a letter ("Lupin Limited Notice Letter") dated October 7, 2009, from Lupin Limited's counsel, Leydig, Voit & Mayer, Ltd., stating that Lupin Limited had filed the Lupin ANDA seeking approval to manufacture, use, offer for sale and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent. The letter notifies Medicis that the Lupin ANDA was submitted with a Paragraph IV certification that the '838 patent purportedly is invalid. The Lupin Limited Notice Letter did not provide a "detailed statement of the factual and legal basis" for any claim of noninfringement of claims 3, 4, 12, and 13 of the '838 patent, as required under 21 U.S.C. § 355(j)(2)(B)(iv)(II).

38. On information and belief, Lupin Pharma participated in, contributed to, aided, abetted, and/or induced Lupin Limited's submission of the Lupin ANDA and its Paragraph IV allegations to the FDA.

39. Lupin Limited and Lupin Pharma have infringed the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their submission of the Lupin ANDA to the FDA for generic SOLODYN™ minocycline HCl extended release tablets that are covered by one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13.

40. Lupin Pharma is jointly and severally liable for any infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Lupin Pharma's participation in, contribution to, aiding,

abetting, and/or inducement of the submission of the Lupin ANDA and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, sale, offer to sell, importation or distribution of products under the Lupin ANDA would infringe one or more of claims 3, 4, 12, and 13 of the '838 patent.

42. Medicis is entitled to an order requiring that Lupin Limited amend its Paragraph IV certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

43. Medicis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Lupin ANDA be a date that is not earlier than the expiration of the '838 patent, or any later period of exclusivity for the '838 patent to which Medicis becomes entitled.

44. Medicis will be irreparably harmed if Lupin Limited and Lupin Pharma are not enjoined from infringing or actively inducing or contributing to infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent. Pursuant to 35 U.S.C. § 283, Medicis is entitled to a permanent injunction against further infringement. Medicis does not have an adequate remedy at law.

45. To the extent Lupin Limited and/or Lupin Pharma commercialize their product, Medicis will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Medicis respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Defendants have infringed one or more of the following claims of the '838 patent: claims 3, 4, 12, and 13, under 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA the Lupin ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, or

distribution in and/or importation into the United States of generic SOLODYN™ minocycline HCl extended release tablets for the treatment of acne before the expiration of the '838 patent;

B. an order requiring that Defendants amend their respective Paragraph IV certifications to Paragraph III certifications as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

C. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Lupin ANDA for generic SOLODYN™ minocycline HCl extended release tablets be a date that is not earlier than the date of the expiration of the '838 patent or any later period of exclusivity to which Medicis is or become entitled;

D. a permanent injunction enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA;

E. an order enjoining Defendants, their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with any of them, from infringing the '838 patent, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the product described in the Lupin ANDA while the litigation is pending;

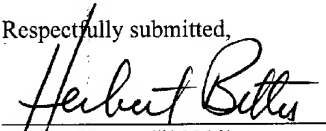
F. a judgment declaring that the manufacture, use, sale, offer to sell, importation or distribution of the products described in the Lupin ANDA would constitute infringement of one or more of claims 3, 4, 12, and 13 of the '838 patent, or inducing or contributing to such conduct, by Defendants pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

G. a judgment declaring this to be an exceptional case;

H.. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284; and

I. such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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November 17, 2009

US005908838A

United States Patent [19]

Gans

[11] Patent Number: 5,908,838

[45] Date of Patent: Jun. 1, 1999

[54] METHOD FOR THE TREATMENT OF ACNE

[75] Inventor: Eugene H. Gans, Phoenix, Ariz.

[73] Assignee: Medics Pharmaceutical Corporation, Phoenix, Ariz.

[21] Appl. No.: 09/028,871

[22] Filed: Feb. 19, 1998

[51] Int. Cl.[6] A61K 31/65

[52] U.S. Cl. 514/152

[58] Field of Search 514/152

[56] References Cited

U.S. PATENT DOCUMENTS

5,518,730 5/1996 Fuisz 424/426

OTHER PUBLICATIONS

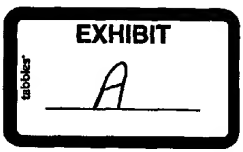
Williams et al., the Lancet, 2(7883) 744–6 Sep. 28, 1974.

Primary Examiner—Phyllis Spivack
Attorney, Agent, or Firm—William J. McNichol, Jr.

[57] ABSTRACT

A method for the treatment of acne is provided which results in the reduction of vestibular side effects following administration of oral tetracycline antibiotics.

18 Claims, No Drawings



METHOD FOR THE TREATMENT OF ACNE

FIELD OF THE INVENTION

This invention relates to methods for the treatment of acne, and in particular to methods for the treatment of acne involving the use of oral tetracycline antibiotics.

BACKGROUND OF THE INVENTION

Oral tetracycline antibiotics are frequently used in the treatment of acne. One of the most effective oral tetracycline antibiotics used in the treatment of acne it is minocycline. All tetracycline antibiotics are known to have some side effects. These side effects include vestibular symptoms such as vertigo, dizziness or blurred vision. These effects are sometimes disabling. See, Gould & Brookler, Arch. Otolarang. Vol. 96, p. 291 (1972); Williams et al., Lancet, Sep. 28, 1974, p. 144–45; Fanning & Gump, Arch. Intern. Med., Vol. 136, pp. 761–62 (1976). Headache and general malaise, along with gastro-intestinal symptoms such as the diarrhea, nausea, gas, or cramps also occur. Dry nose and dry mouth are also occasionally encountered.

Dosage forms of oral tetracycline antibiotics are typically constructed with a view towards achieving rapid dissolution rates. Rapid dissolution is believed to be essential to the effectiveness of these drugs. The driving force behind this practice is the understanding that rapid dissolution leads to rapid assimilation through the gut lining, where the antibiotics are then transmitted through the blood stream to the skin, where they are active against bacteria associated with acne. The U.S. Food and Drug Administration (FDA) has established standards for dissolution rates for various oral antibiotics. These standards set minimum dissolution rates. For example, the FDA standard for oral minocycline is that 75 percent of the stated dosage must have dissolved within 45 minutes, under standard U.S. Pharmacopea test conditions. Commercial products are typically engineered to have a dissolution rates which are substantially faster than that required by the FDA. All of this is based upon the generally accepted belief in the art that, while dissolution rates enhance the effectiveness of the antibiotic, once the FDA minimum dissolution rate is achieved, all products have equivalent safety and efficacy.

SUMMARY OF THE INVENTION

It has been discovered that the dissolution rate of oral tetracycline antibiotics, especially minocycline, can affect the occurrence of vestibular side effects. Specifically, too rapid dissolution of oral tetracyclines increases the incidence and severity of vestibular side effects. By reducing or slowing the dissolution rates of the antibiotics, the incidence and/or severity of vestibular side effects can be reduced significantly.

DETAILED DESCRIPTION OF THE INVENTION

Vestibular reactions are an undesirable and sometimes seriously disconcerting side effect of minocycline therapy. According to the present invention, it is possible to provide persons susceptible to such side effects with the benefits of minocycline therapy while diminishing the incidence and/or severity of these side effects. This is accomplished by adjusting the dissolution rate of the minocycline in its dosage form so that, while an effective concentration of minocycline is achieved in the blood stream of the patient, vestibular side effects are greatly reduced.

In a preferred embodiment of the invention, the minocycline dissolves at a rate of only 15 percent within the first 15 minutes, 35 percent within 30 minutes, 50 percent within 45 minutes, and 80 percent within one hour. It is also advantageous to use a dissolution rate of 20 percent within 15 minutes, 50 percent in 30 minutes, 75 percent within 45 minutes and 100 percent dissolution within 60 minutes. Dissolution rates as fast as 30 percent within 15 minutes, 60 percent within 30 minutes, 75 percent within 45 minutes and complete dissolution within 60 minutes or even as fast as 35 percent within 15 minutes, 80 percent within 30 minutes and substantially complete dissolution within 45 minutes can be used. Preferred dissolution rates are within the range of 20 to 40 percent in 15 minutes, 50 to 80 percent in 30 minutes, and 70 to 95 percent in 45 minutes. Faster rates of 25 to 35 percent in 15 minutes, 60 to 80 percent in 30 minutes and 80 to 100 percent in 45 minutes are useful. It will be understood however, that the faster dissolution rates do not achieve as significant a reduction in the reduction of unwanted side effects as the slower dissolution rates.

Minocycline is available from a variety of sources. Various commercial products containing minocycline as their active ingredient have a variety of the dissolution rates. In the following example, slower dissolving minocycline is compared with fast-dissolving minocycline.

A blinded cross-over study of the vestibular side effects of minocycline involving 32 female subjects was conducted. The subjects were given either a fast dissolving or a slower dissolving dosage form of minocycline. The doses for the subjects were adjusted on the basis of each subject's total body weight and were in the range typically used for the treatment of severe acne. Subjects weighing 50 to 69 kg were given one-hundred milligrams. Subjects weighing 70 to 89 kg, the dose were given one hundred fifty milligrams and subjects above received 90 kilograms, 200 milligrams. This dose was given once a day at 5 p.m. Subjects received one of the two dose forms for four days. After a two week washout, each group "crossed over" and received the dosage form that they had not received during the first four day period. Each subject was required to maintain an accurate diary of vestibular side effects. The diary recorded the number of days that each subject experienced vestibular side effects and the number of incidents of each symptom. The 32 subjects were evaluated over a five day period, yielding 160 person-day measurements per treatment group. The number of days that each subject recorded a side effect and the severity of that side effect the reported in Table 1.

From Table 1 it can be seen that a total of 27 incidents of vestibular side effects occurred in the fast dissolving treatment group, compared to only five incidents in the slower dissolving group. The severity of the vestibular side effects are reported on a scale of 1 to 4. With 1 indicating slight severity, 2 indicating mild severity, 3 moderate, and 4 severe side effects.

The dissolution rates for the fast dissolving dosage form and the slower dissolving dosage form are set forth below.

TABLE 1

	Vestibular Side Effects			
Symptom	Severity	No. of Time Intervals	Duration	Severity Category
	Patients Treated With Slower-Dissolving Minocycline			
dizziness	slight	2	8:00 am–4:00 pm	1
dizziness	slight-mild	4	all day	1.5
dizziness	mild	1	on and off	2
dizziness	slight	1	all evening	1

TABLE 1-continued

Symptom	Severity	Vestibular Side Effects No. of Time Intervals	Duration	Severity Category
dizziness	slight-mild	2	morning thru mid day	1.5
	Patients Treated With Fast-Dissolving Minocycline			
dizziness	slight	2	7:00 am–12:00 pm	1
blurred vision	slight-mild	2	8:00 am–3:00 pm	1.5
dizziness	slight	2	7:00 am–12:00 pm	1
dizziness	slight	2	8:00 am–2:00 pm	1
dizziness	slight	2	7:00 am–2:00 pm	1
dizziness	slight	2	7:00 am–3:00 pm	1
dizziness	slight	2	morning-late afternoon	1
dizziness	slight	2	morning-late afternoon	1
dizziness	slight	2	morning-late afternoon	1
dizziness	slight	1	1 hour	1
dizziness	slight	1	2 hours	1
dizziness	slight	1	about 1–2 hours	1
dizziness	slight	1	about 1.5 hours	1
dizziness	slight	1	2 hours	1
blurred vision	slight	1	1 hour	1
dizziness	slight	1	2 hours	1
dizziness	slight-mild	2	7.5 hours	1.5
dizziness	mild	1	6:00 am–8:00 am	2
vertigo	mild	1	2:00 am–8:00 am	2
dizziness	mild	1	6:00 am–8:00 am	2
vertigo	mild	1	2:00 am–8:00 am	2
dizziness	mild	1	6:00 am–8:00 am	2
vertigo	mild	1	6:00 am–8:00 am	2
dizziness	mild	1	6:00 am–8:00 am	2
vertigo	mild	1	6:00 am–8:00 am	2
dizziness	mild	1	6:00 am–8:00 am	2
vertigo	mild	1	6:00 am–8:00 am	2

TABLE 2

Fast Dissolving		Slow Dissolving	
Time (Min.)	% Dissolution	Time (Min.)	% Dissolution
0	0.0	0	0.0
15	100	15	30
30	100	30	67
45	100	45	88
60	100	60	95

The cause of the effectiveness of this invention is not known. However, it can be speculated that the dissolution rates called for by the present invention allow the vestibular organs to acclimate themselves to the presence of the minocycline, and thereby avoid unwanted side effects. This explanation is consistent with the avoidance of vestibular side effects even through the use of both slow and fast dissolving dosage forms may achieve the same level of minocycline in the blood stream.

The foregoing example is given by way of illustration only. The scope of the invention is defined only by the following claims.

I claim:

1. A method for reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics, comprising administering the oral tetracycline antibiotic in a slowly dissolving dosage form.

2. The method of claim **1**, wherein the oral tetracycline antibiotic is minocycline.

3. The method of claim **2**, wherein the antibiotic dissolves at a rate no faster than 15 percent in 15 minutes, 35 percent in 30 minutes, 50 percent in 45 minutes and 80 percent in 60 minutes.

4. The method of the claim **2** wherein the antibiotic dissolves at a rate no faster than 20 percent in 15 minutes, 50 percent in 30 minutes, and 75 percent in 45 minutes.

5. The method of claim **2** wherein and the antibiotic dissolves at a rate no faster than 30 percent in 15 minutes, 60 percent in 30 minutes, and 75 percent in 45 minutes.

6. The method of the claim **2** wherein the antibiotic dissolves at a rate no faster than 35 percent in 15 minutes, 80 percent in 30 minutes, and one hundred percent in 45 minutes.

7. The method of claim **2**, wherein the antibiotic dissolves at a rate within the range of 20 to 40 percent in 15 minutes, 50 to 80 percent in 30 minutes, 70 to 95 percent in 45 minutes and 95 to 100 percent in 60 minutes.

8. The method of the claim **2** wherein the antibiotic dissolves at a rate within the range of 25 to 35 percent in 15 minutes, 60 to 80 percent in 30 minutes, and 80 to 100 percent in 45 minutes.

9. The method of claim **2** wherein and the antibiotic dissolves at a rate within the range of 30 to 35 percent in 15 minutes, 65 to 75 percent in 30 minutes, and 90 to 100 percent in 45 minutes.

10. A method for reducing the incidence or severity of vestibular side effects resulting from the treatment of acne by the use of oral tetracycline antibiotics, comprising administering the oral tetracycline antibiotic in a slowly dissolving dosage form, wherein the dissolution of the antibiotic is substantially complete in less than 24 hours.

11. The method of claim **10**, wherein the oral tetracycline antibiotic is minocycline.

12. The method of claim **11**, wherein the antibiotic dissolves at a rate no faster than 15 percent in 15 minutes, 35 percent in 30 minutes, 50 percent in 45 minutes and 80 percent in 60 minutes.

13. The method of the claim **11** wherein the antibiotic dissolves at a rate no faster than 20 percent in 15 minutes, 50 percent in 30 minutes, and 75 percent in 45 minutes.

14. The method of claim **11** wherein and the antibiotic dissolves at a rate no faster than 30 percent in 15 minutes, 60 percent in 30 minutes, and 75 percent in 45 minutes.

15. The method of the claim **11** wherein the antibiotic dissolves at a rate no faster than 35 percent in 15 minutes, 80 percent in 30 minutes, and one hundred percent in 45 minutes.

16. The method of claim **11**, wherein the antibiotic dissolves at a rate within the range of 20 to 40 percent in 15 minutes, 50 to 80 percent in 30 minutes, 70 to 95 percent in 45 minutes and 95 to 100 percent in 60 minutes.

17. The method of the claim **11** wherein the antibiotic dissolves at a rate within the range of 25 to 35 percent in 15 minutes, 60 to 80 percent in 30 minutes, and 80 to 100 percent in 45 minutes.

18. The method of claim **11** wherein and the antibiotic dissolves at a rate within the range of 30 to 35 percent in 15 minutes, 65 to 75 percent in 30 minutes, and 90 to 100 percent in 45 minutes.

* * * * *

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

FILED
U.S. DISTRICT COURT
DISTRICT OF MARYLAND
2009 NOV 17 P 12:26
CLERK'S OFFICE
AT BALTIMORE
BY _____ DEPUTY

I. (a) PLAINTIFFS

Medicis Pharmaceutical Corporation

(b) County of Residence of First Listed Plaintiff Maricopa County, AZ
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

See Attachment

DEFENDANTS

Lupin Ltd., Lupin Pharmaceuticals, Inc.

County of Residence of First Listed Defendant n/a
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

See Attachment

JFM 09CV3052

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt. Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty	IMMIGRATION	☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other	☐ 462 Naturalization Application		☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights	☐ 463 Habeas Corpus - Alien Detainee		☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition	☐ 465 Other Immigration Actions		

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
35 U.S.C. §271

Brief description of cause:
Patent Infringement suit

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $ Injunctive relief and declaratory judgment

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☑ No

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE
11/17/2009

SIGNATURE OF ATTORNEY OF RECORD
Herbert Beltz

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

ATTACHMENT TO CIVIL COVER SHEET

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Northern Division

MEDICIS PHARMACEUTICAL CORPORATION,
7720 North Dobson Road
Scottsdale, Arizona 85256

Plaintiff,

v.

JFM 09CV3062

CIVIL ACTION NO. _____

LUPIN LTD.,
B/4 Laxmi Towers
Bandra Kurla Complex
Mumbai 400 051
India

Serve:
Dr. Desh Bandhu Gupta, Chairman
Lupin, Ltd.
Laxmi Towers "B" Wing, 5th Floor
Bandra Kurla Complex
Mumbai 400 051
India

OR

Serve Resident Agent:
Robert F. Green
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza, Suite 4900
180 N. Stetson Avenue
Chicago, Illinois 60601-6731

And

LUPIN PHARMACEUTICALS INC.,
Harborplace Tower, 21st Floor,
111 South Calvert Street
Baltimore, Maryland 21202

Serve Registered Agent:
Vinita Gupa
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, Maryland 21202

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Medicis Pharmaceutical Corporation ("Medicis") for its Complaint against Defendants Lupin Ltd. ("Lupin Limited") and Lupin Pharmaceuticals Inc. ("Lupin Pharma") (collectively, the "Defendants") alleges as follows:

I. THE PARTIES

1. Medicis is a Delaware corporation with its principal place of business at 7720 North Dobson Road, Scottsdale, Arizona 85256. Medicis is a leading independent specialty pharmaceutical company in the United States focusing on the treatment of dermatological conditions. Medicis's products have earned wide acceptance by both physicians and patients, including Medicis's SOLODYN™ extended release tablets for acne treatment.

2. Defendant Lupin Limited is a corporation organized and existing under the laws of India, with corporate offices located at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai 400 051, India, and registered offices located at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. Lupin Limited is in the business of manufacturing pharmaceutical drugs, including generic pharmaceutical drugs, that it markets, distributes, and sells in the State of Maryland and throughout the United States.

3. Defendant Lupin Pharma is a corporation organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, MD 21202, and is a wholly-owned subsidiary of Lupin Limited. Lupin Pharma is in the business of marketing, distributing, and selling, in the State of Maryland and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs, manufactured by Lupin Limited. Lupin Pharma is also the United States agent for Lupin Limited for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

4. On information and belief, Lupin Limited and Lupin Pharma collaborate to manufacture, import, market, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved abbreviated new drug applications) in the State of Maryland and the United States.

II. NATURE OF THE ACTION

5. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, et seq.) based upon Defendants' infringement of one or more of claims 3, 4, 12, and 13 of Medicis's U.S. Patent No. 5,908,838, entitled "METHOD FOR THE TREATMENT OF ACNE" ("the '838 patent"), relating generally to the field of acne treatment.

6. Lupin Limited, by and with Lupin Pharma, filed Abbreviated New Drug Application No. 91-424 (the "Lupin ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell a generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne. Lupin Limited and Lupin Pharma have infringed one or more of claims 3, 4, 12, and 13 of the '838 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of the Lupin ANDA with a Paragraph IV certification and seeking U.S. Food and Drug Administration ("FDA") approval of the Lupin ANDA prior to the expiration of the '838 patent.

III. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over Medicis's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Lupin Pharma by virtue of, inter alia, Lupin Pharma having its principal place of business at Harborplace Tower, 21st Floor, 111 South Calvert Street, Baltimore, Maryland, having conducted business in Maryland, having availed itself of the rights and benefits of Maryland law, and having engaged in substantial and continuing contacts with the State.

9. This Court has personal jurisdiction over Lupin Limited for a variety of reasons. First, Lupin Limited has previously consented to this Court's jurisdiction and thus taken advantage of the rights and protections provided by this Court. Second, Lupin Limited does substantial business, derives substantial revenue, and engages in persistent conduct in Maryland, with and through Lupin Pharma as well as through sales to Maryland residents. Third, the infringement claims alleged in this action arise partially out of Lupin Limited's actions in Maryland. Finally, Lupin Limited has such substantial control over Lupin Pharma to justify treating Lupin Pharma as a mere alter ego of Lupin Limited and imputing Lupin Pharma's Maryland contacts to Lupin Limited.

10. Lupin Limited has previously consented to this Court's jurisdiction and availed itself of this Court's protections. See, e.g., Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-1258-JFM (D. Md.); Abbott Labs. v. Lupin Ltd., Civil Action No. 09-564-WMN (D. Md.); Genzyme Corp. v. Lupin Ltd., Civil Action No. 09-563-JFM (D. Md.); Sciele Pharma, Inc. v. Lupin Ltd., Civil Action No. 09-105-AMD (D. Md.). Lupin Limited has also *de facto* acknowledged that it is subject to personal jurisdiction in Maryland by twice moving to transfer cases to Maryland pursuant to 28 U.S.C. § 1404(a). See Abbott Labs. v. Lupin Ltd., C.A. No. 09-152-JJF (D. Del.); Sciele Pharma, Inc. v. Lupin Ltd., C.A. No. 06-37-JJF (D. Del.); see also 28 U.S.C. § 1404(a) (allowing district court to "transfer any civil action to any other district or division where it might have been brought") (emphasis added).

11. On information and belief, by its relationship with Lupin Pharma and its sales to Maryland residents, Lupin Limited does substantial business in Maryland, derives substantial revenue from Maryland, and engages in other persistent courses of conduct in Maryland. Pursuant to the Maryland Long Arm statute, which is co-extensive with the limits of due process, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortuous injury . . . if he regularly does or solicits business, engages in any other persistent course of conduct in the State or

derives substantial revenue from goods, food, services, or manufactured products used or consumed in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(4). Lupin Limited regularly does millions of dollars of business in Maryland through its relationship with and control over Lupin Pharma, and through it sales to Maryland residents, by and through Lupin Pharma. For the same reasons, Lupin Limited also derives substantial revenue from its business in Maryland. Finally, Lupin Limited engages in a persistent course of conduct in Maryland by regularly filing ANDAs with the FDA in Maryland, by and through its agent, Lupin Pharma. These continuous and systematic contacts, including but not limited to those described above and below, are more than sufficient for this Court to exercise general personal jurisdiction over Lupin Limited.

12. On information and belief, the claims in this action partially arise out of acts committed by Lupin Limited and its agent, Lupin Pharma, in Maryland. Pursuant to the Maryland Long Arm Statute, Maryland can exercise personal jurisdiction over persons who "directly or by an agent . . . [c]ause[] tortious injury in the State by an act or omission in the State." Md. Code Ann., Cts. & Jud. Proc. § 6-103(b)(3). On information and belief, Lupin Limited's relationship with and control over Lupin Pharma, and the plan and agreement between the two to develop, manufacture, acquire approval, and sell the disputed generic pharmaceutical drug occurred in part in Maryland, and caused tortious injury to Medicis. Moreover, on information and belief, Lupin Limited will, following any FDA approval of the Lupin ANDA, sell the generic product that is the subject of the infringement claims in this action in the State of Maryland and throughout the United States, using Lupin Pharma as its marketer, distributor, and seller. Finally, Lupin Pharma, as Lupin Limited's authorized agent and thus acting as Lupin Limited, participated in Maryland in the preparation and/or submission of the Lupin ANDA, which constitute acts in Maryland that directly give rise to Medicis's present claims of patent infringement.

13. Lupin Limited is also subject to general jurisdiction in Maryland because, on information on belief, Lupin Pharma is a mere alter ego of Lupin Limited, and this Court can impute Lupin Pharma's Maryland contacts to Lupin Limited. In support, Medicis pleads the following:

14. Lupin Limited is in the business of developing, manufacturing, marketing, and selling pharmaceutical drugs. On information and belief, Lupin Limited established Lupin Pharma for the sole purpose of distributing, marketing, and selling its pharmaceutical drug products, including generic drug products, in the United States;

15. On information and belief, Lupin Pharma is entirely reliant on Lupin Limited as the source of its products. On information and belief, there is no independent reason for the existence of Lupin Pharma except to function as the U.S.-based marketing, sales, and distribution arm for Lupin Limited and to serve as agent for Lupin Limited's ANDAs;

16. On information and belief, Lupin Limited exercises considerable control over Lupin Pharma, and approves significant decisions of Lupin Pharma such as allowing Lupin Pharma to act as the agent for Lupin Limited in connection with preparing and filing the Lupin ANDA, and acting as Lupin Limited's agent in the United States;

17. Lupin Limited knew that Lupin Pharma's principal place of business was in Maryland;

18. Lupin Limited and Lupin Pharma hold themselves out as a unitary entity and have represented to the public that the activities of Lupin Limited and Lupin Pharma are directed, controlled, and carried out by a single entity, namely, Lupin Limited. For example, Lupin Limited maintains an Internet website at the URL www.lupinworld.com at which Lupin Limited describes Lupin Pharma as a "Business Segment" of Lupin Limited. Moreover, the President and CEO of Lupin Pharma, Vinita Gupta, is held out in Lupin Limited's Annual Report as part of Lupin Limited's "Senior Management Team;"

19. On information and belief, Lupin Limited maintains and controls a broad distribution network in the United States for Lupin Limited's products that annually results in the distribution and sale of millions of dollars of Lupin Limited products. On information and belief, Lupin Limited's business and market strategy includes the distribution, through Lupin Pharma, of substantial volumes of Lupin Limited's pharmaceutical drug products in Maryland and the United States. In this way, Lupin Pharma is an integral part of Lupin Limited's business;

20. On information and belief, Lupin Pharma is actively involved with planning Lupin Limited's new products and filing the Lupin ANDA for the generic drug in dispute and the ANDAs for other drugs;

21. Lupin Pharma's President and CEO, Vinita Gupta, is a member of the Board of Directors of Lupin Limited;

22. Lupin Pharma's President and CEO, Vinita Gupta, is the daughter of Lupin Limited's Chairman, and the brother of Lupin Limited's Executive Director;

23. On information and belief, Lupin Limited in entirely reliant on Lupin Pharma for access to the lucrative U.S. market, and sells or distributes few, if any, products to the U.S. market except through Lupin Pharma;

24. On information and belief, Lupin Limited uses Lupin Pharma as its resident agent for each and every ANDA filing;

25. On information and belief, the products manufactured by Lupin Limited and sold, directly or indirectly through Lupin Pharma in the United States and Maryland, indicate that they are manufactured by Lupin Limited; and

26. On information and belief, Lupin Pharma acted in concert with Lupin Limited to develop Lupin Limited's generic version of SOLODYN™ minocycline HCl extended release tablets for the treatment of acne, and to seek approval from the FDA to sell Lupin Limited's generic version of

SOLODYN™ minocycline HCl extended release tablets for the treatment of acne in the State of Maryland and throughout the United States.

27. Additionally, and in the alternative, Medicis alleges that to the extent Lupin Limited is not subject to the jurisdiction of the courts of general jurisdiction of the State of Maryland, Lupin Limited likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

28. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

IV. THE PATENT-IN-SUIT (U.S. PATENT NO. 5,908,838)

29. The allegations of ¶¶ 1-28 are incorporated herein by reference.

30. Medicis is the owner of all right, title and interest in the '838 patent. The United States Patent and Trademark Office duly and legally issued the '838 patent on June 1, 1999, to Eugene H. Gans, which was assigned to Medicis. A true and correct copy of the '838 patent is attached as Exhibit A.

31. On May 8, 2006, the FDA approved Medicis's new drug application 50-808 for SOLODYN™ minocycline HCl extended release tablets under § 505(b) of the FFDCA, 21 U.S.C. § 355(b), for the treatment of acne.

32. The use of SOLODYN™ minocycline HCl extended release tablets is covered by the '838 patent, and Medicis has the right to enforce the '838 patent.

33. The FDA listed the '838 patent in the Orange Book on December 3, 2008.

34. On information and belief, Defendants submitted the Lupin ANDA to the FDA after the '838 patent was listed in the Orange Book.